



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,106	09/28/2000	Randal K. Buddington	2343-104-27	8636

7590 01/14/2002

Patent Prosecution Services  
Piper Marbury Rudnick & Wolfe LLP  
1200 Nineteenth Street, N.W.  
Washington, DC 20036-2412

EXAMINER

EVANS, CHARESSE L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/14/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/671,106	BUDDINGTON ET AL.
	Examiner Charesse L. Evans	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 October 2001.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 and 4-22 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1 and 4-22 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Action Summary*

The rejection of record under 35 USC 112, second paragraph, is withdrawn.

Acknowledgement is made of the cancellation of claims 2 and 3.

### *Response to Arguments*

Applicant's arguments filed October 31, 2001, have been fully considered but they are not persuasive. In this instance, applicant argues that the fiber-containing nutritional composition disclosed in the prior art is "... used to maintain gut function and to clear toxins by providing stool bulk and substrate for intestinal flora...therefore, used only to treat local infections....". Examiner disagrees with applicant's argument. When an individual ingests the composition, it is inherent to receive the body-wide therapeutic benefits associated with consuming such a composition. While the colon, in many instances, does receive local benefits from administration of the composition, the colon also serves as a pathway by which the composition, with all of its therapeutic benefits, are delivered to the rest of the body, as a whole. Applicant has not demonstrated any unexpected results obtained by using the claimed product over the product disclosed in the prior art.

Applicant further argues that the claimed degree of polymerization of the dietary fibers (inulin) does have an effect on the prevention and/or inhibition of systemic infections. What is the criticality of using fiber with this parameter? Applicant has not shown any unexpected results obtained by utilizing inulin products with the claimed average DP (degree of polymerization).

The rejection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 5,792,754). The claims are directed to a mixture of dietary fibers and methods of using the dietary fibers to treat, prevent and inhibit systemic infections in humans or vertebrates.

Green teaches a nutritional composition containing dietary fibers such as gum arabic, pectin, cellulose, hemicellulose, polysaccharides, oligosaccharides such as inulin and hydrolyzed inulin, resistant starch, lignin, levan or fructan, and carageenans

(columns 2-3). The composition of the reference may be administered via tube feeding or oral consumption (column 2, lines 19-24). Furthermore, this composition, rich in dietary fiber, may be used to clear toxic compounds from the intestines by providing stool bulk and substrate for intestinal flora (column 1, lines 12-15).

Green discloses a fibrous composition that is basically the same as that recited in the claims, except that it does not expressly teach inulin with an average degree of polymerization. It is the position of the examiner, however, that this parameter fails to impart a patentable characteristic. As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute key components of the referenced invention for key components of the claimed invention. One having ordinary skill in the art would have been motivated to make such a substitution with the objective of providing a synergistic combination of fibrous material to aid in gut function and maintenance of optimal intestinal wall conditions.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as every element of the invention has been taught by the teachings of the reference.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

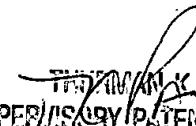
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on M-Thur 7:00a - 4:30p; Alternating F 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

cle  
January 13, 2002



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600